PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES) USER GUIDE

NOVEMBER 2020

VERSION 2.1

Office of Information Technology

DOCUMENT REVISIONS

Date	User Guide Version Number	Document Changes
03/02/2018	0.1	Initial Draft
03/09/2018	0.2	Rev 1. Christo Andonyadis corrections
03/10/2018	0.3	Rev 2. Added sections
03/30/2018	0.4	Rev 3. Added Christo Andonyadis corrections and comments
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7/1/2020	2.0	Initial 2.0 Draft
08/03/2020	2.0	Production
11/01/2020	2.1	Draft
11/10/2020	2.1	

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INTRODUCTION

Patient Registration and Enrollment System (PRES) is an application that allows the user to register and enroll patients into trial protocols.

The user interface (UI) is a Web Application compatible with Google Chrome, Microsoft Edge, Mozilla Firefox, and Apple Safari. It has been developed by the Office of Information Technology, CCR, NCI, NIH, that also supports and updates the system.

GETTING TO PRES

To access PRESS, open your preferred Web Browser and enter https://pres.ccr.cancer.gov in the URL bar. PRES is only accessible while connected to the NIH network.

LOGIN

Users are prompted to login by entering a Username and Password (NIH username and password).

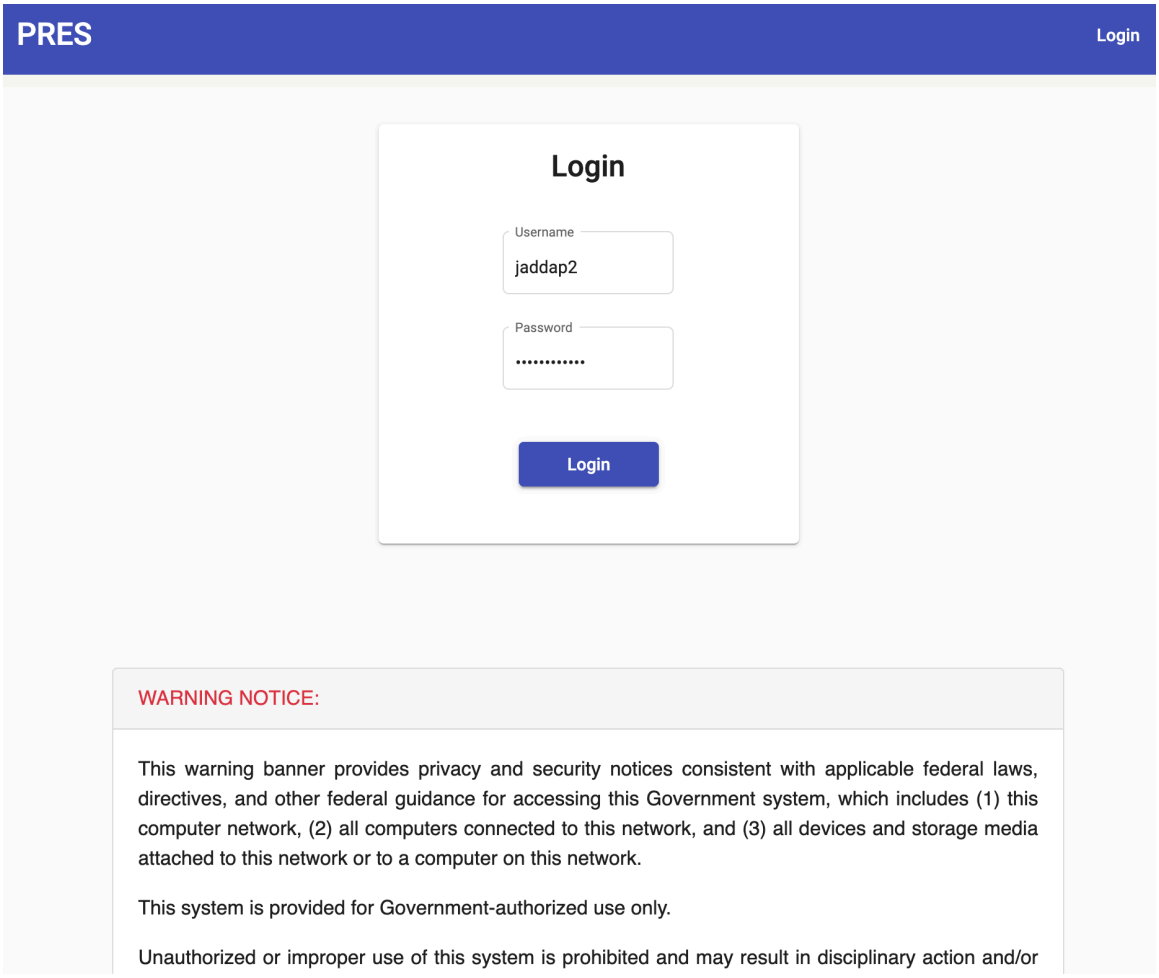
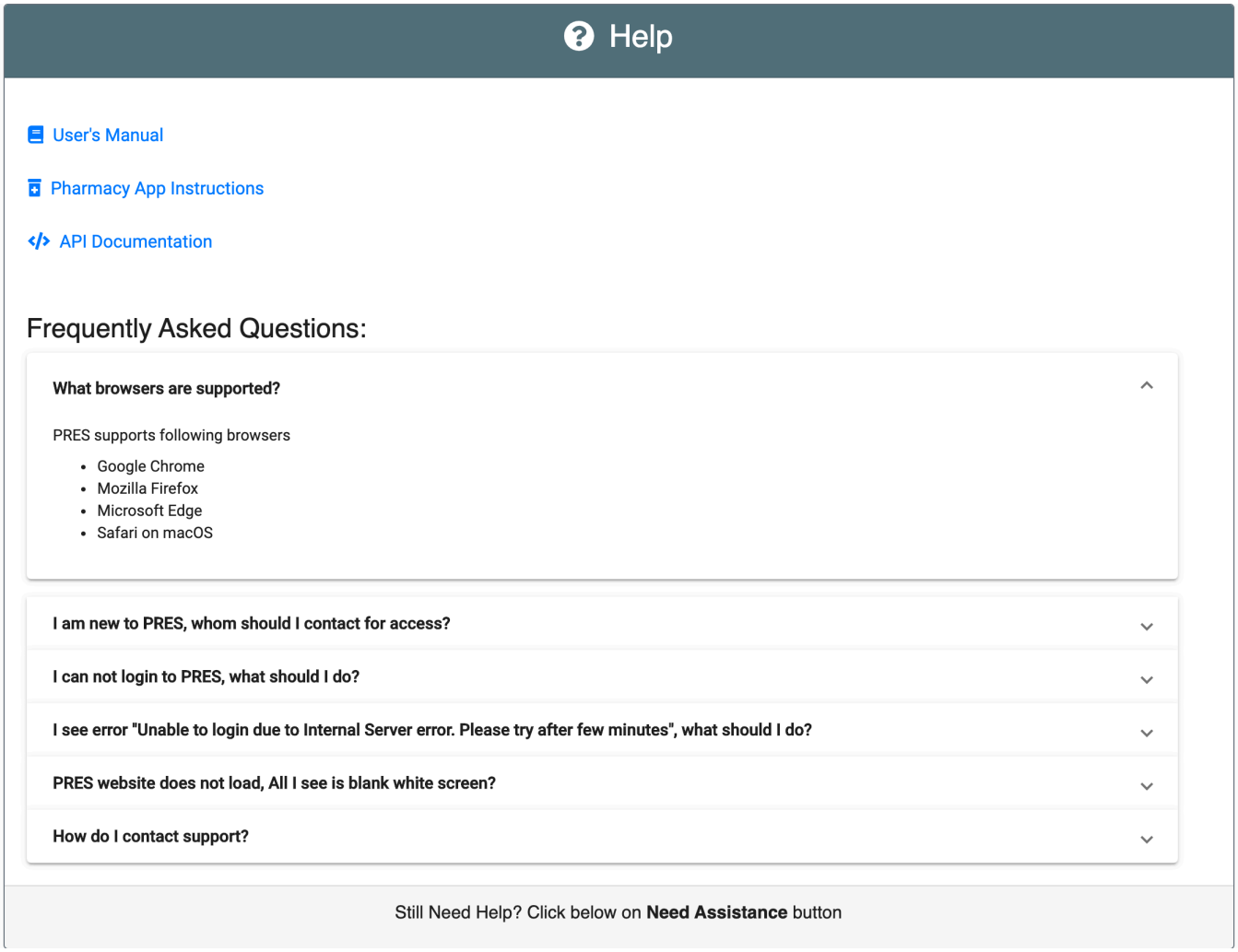


FIGURE 1 - LOGIN SCREEN

If you are not able login or you receive an error message, please use the “Need assistance? Click here!” button located at the lower left part of the home page. This will display the Issues and Feedback menu. Help button also present in upper right side before Login/Logout button on every page. Help page lists User Manual link, API Documentation, Pharmacy App Instructions and frequently asked questions (FAQs)



USEFUL LINKS

At the bottom of the login page and every page in the application, the user will find links to useful functions, policies and organizations.

HOME PAGE

After entering a valid Username and Password, the system will redirect you to the home page. The tiles on the home page will enable the user to access different sections based on the user's privileges. The tiles that appear in the figure below belong to a System Admin. Other users will not be able to see all sections.

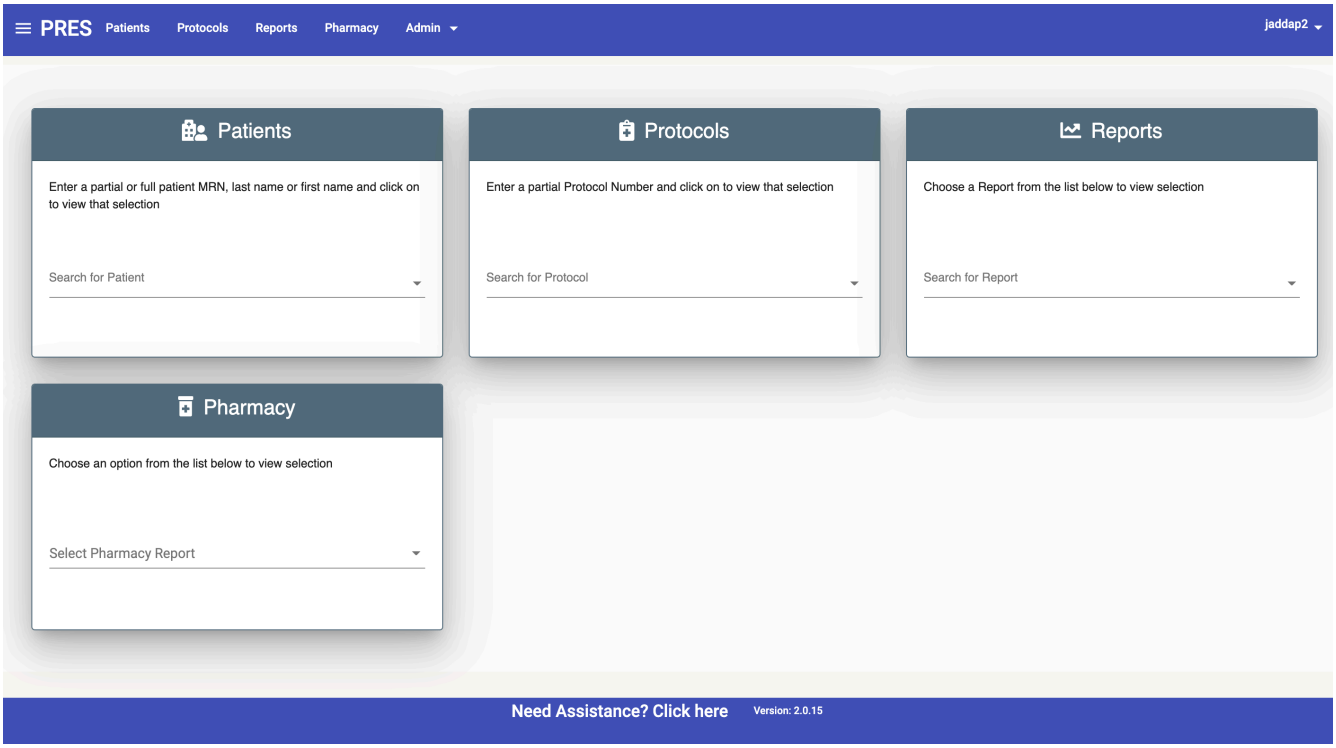


FIGURE 4 – ADMIN HOME PAGE

On every page of the application the user can go back to the home page by clicking the PRES link at the top of every page.

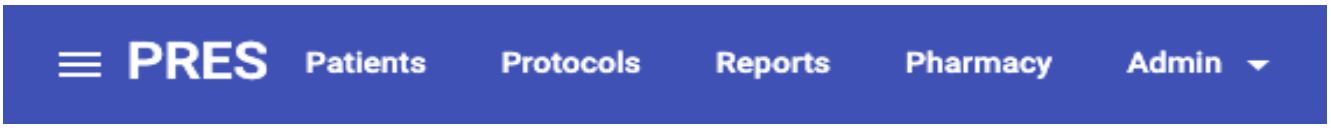


FIGURE 5 – MENU BANNER

The other links provide shortcuts to each page in the application.

Clicking the list icon in the title bar opens yet another navigation shortcut as seen below.

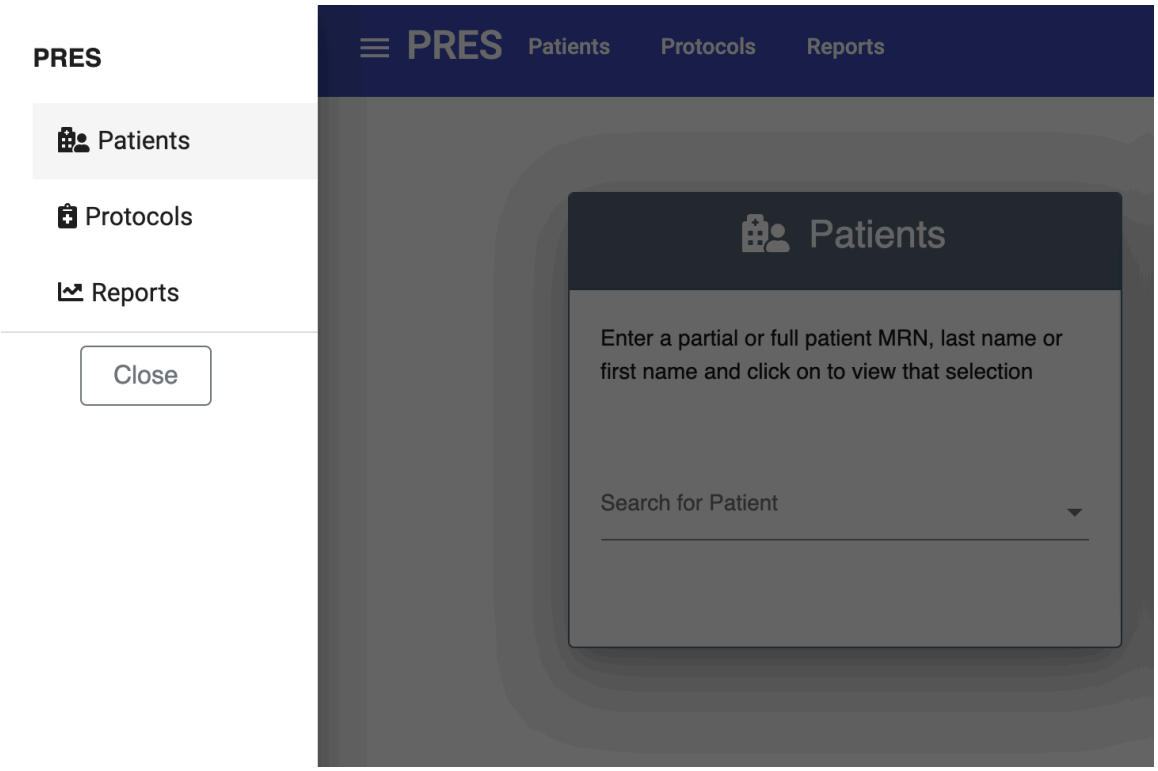


FIGURE 6 – SIDE MENU

The Patients tile on the home page allows the user to search for patients with partial (at least 2 characters) MRN or name.

The Protocols tile allows the user to search protocols by partial protocol number with or without dashes.

The Reports tile (for those with the privilege) allows the user to select and run standard reports.

The Pharmacy tile allows pharmacy users to quickly find new registrations.

There is no Register tile because the user must first select a patient or a protocol before the Register button is available.

SEARCHING AND SELECTING A PATIENT

You can find a patient in 3 different ways in PRES. First, on home page in Patients tile, Second on patient view page and Third on registration page.

To find a patient enter at least 2 characters which will open a drop-down list of patients already in PRES matching those characters:

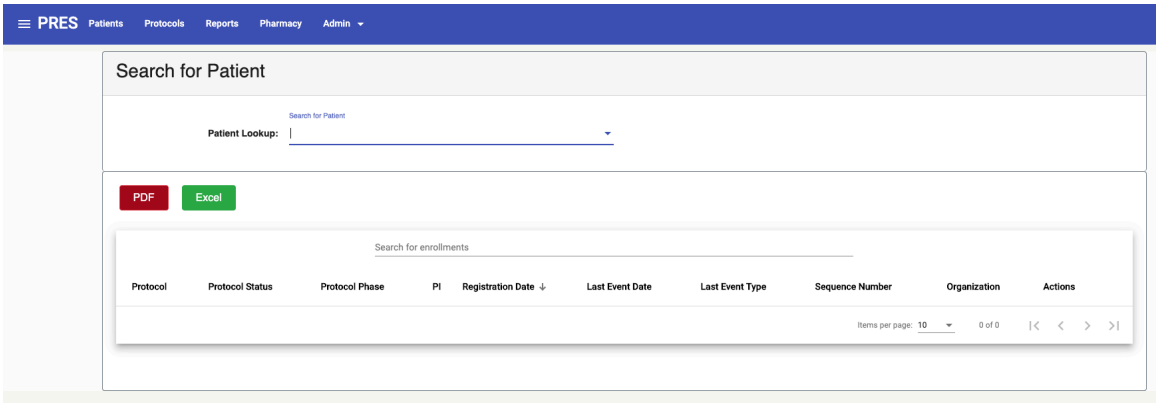


FIGURE 7 – MATCHING PATIENTS IN PRES

Select a patient by clicking on it or continue entering characters until the desired patient is found.

If a valid CRIS MRN is entered that is NOT found in PRES, the search result will indicate “CRIS” as the source of the patient as follows:

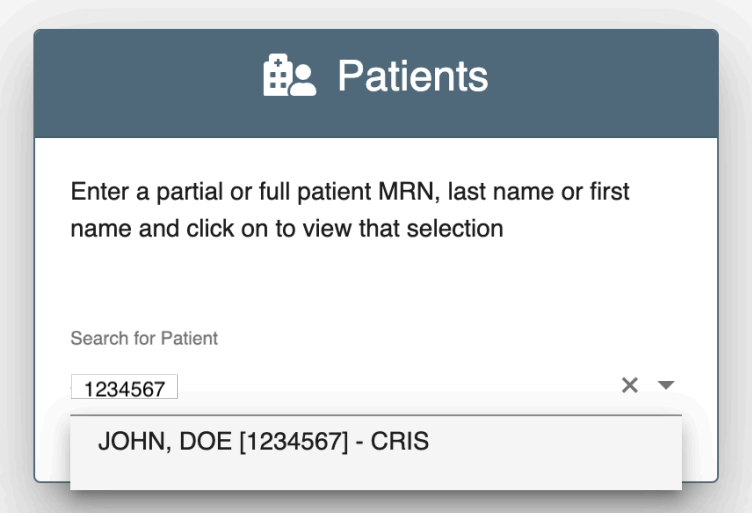


FIGURE 7 – CRIS PATIENT NOT IN PRES

Selecting a CRIS patient will import that patient into PRES.

If a valid CRIS MRN is entered and not found, please contact CRIS to verify the MRN.

If an outside patient is not found in PRES, the user is directed to select a multisite protocol first:

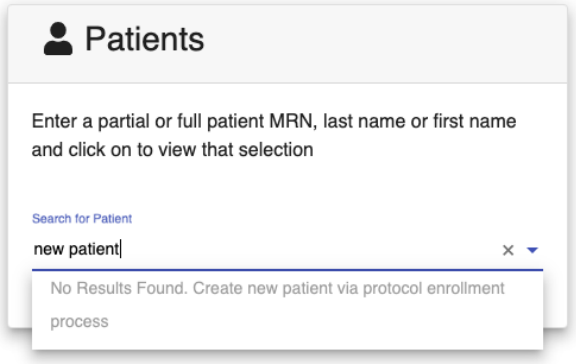


FIGURE 8 - ADDING A PATIENT

Selecting a patient will open the Patient View

ADDING AN OUTSIDE PATIENT

Outside patients can ONLY be created while registering an outside patient to a multisite protocol after selecting an outside Institution:

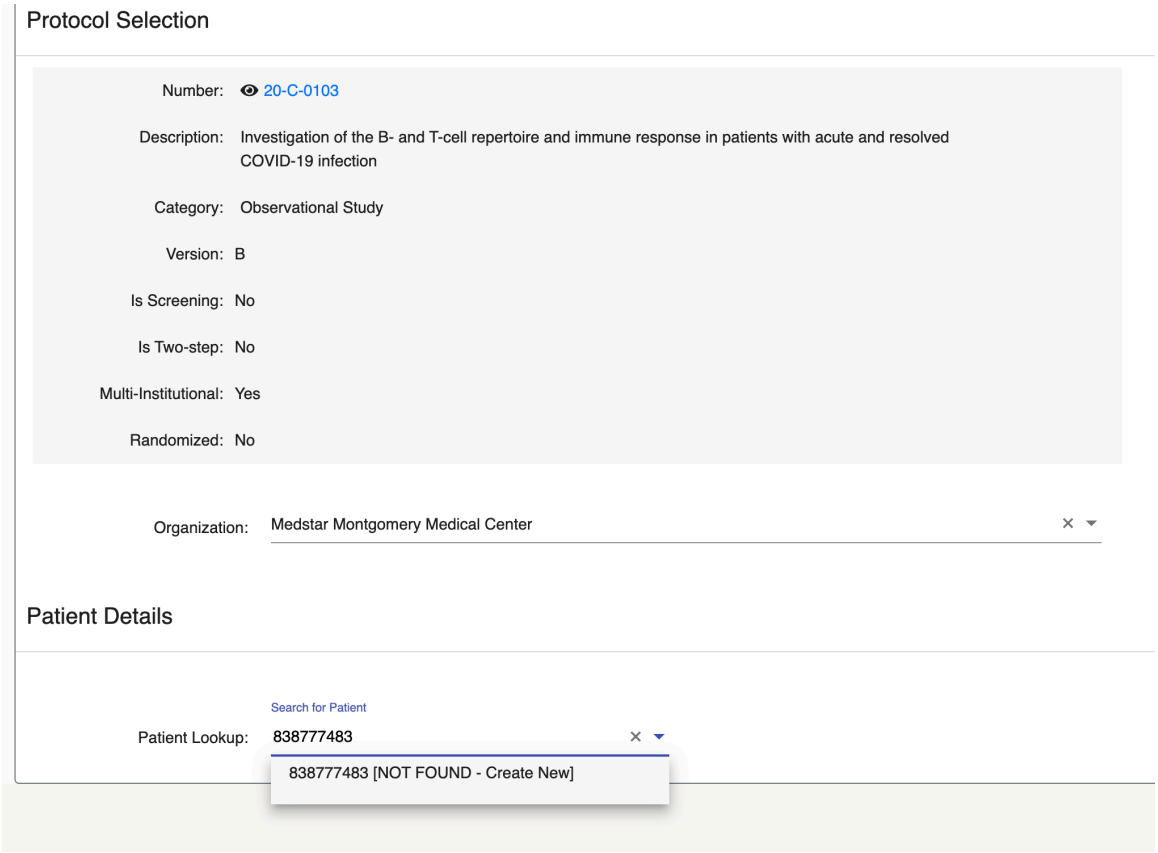


FIGURE 9 - ADDING A PATIENT

After clicking "(NOT FOUND – Create New)" in the Patient Lookup drop down the user will be able to enter the outside patients' demographics:

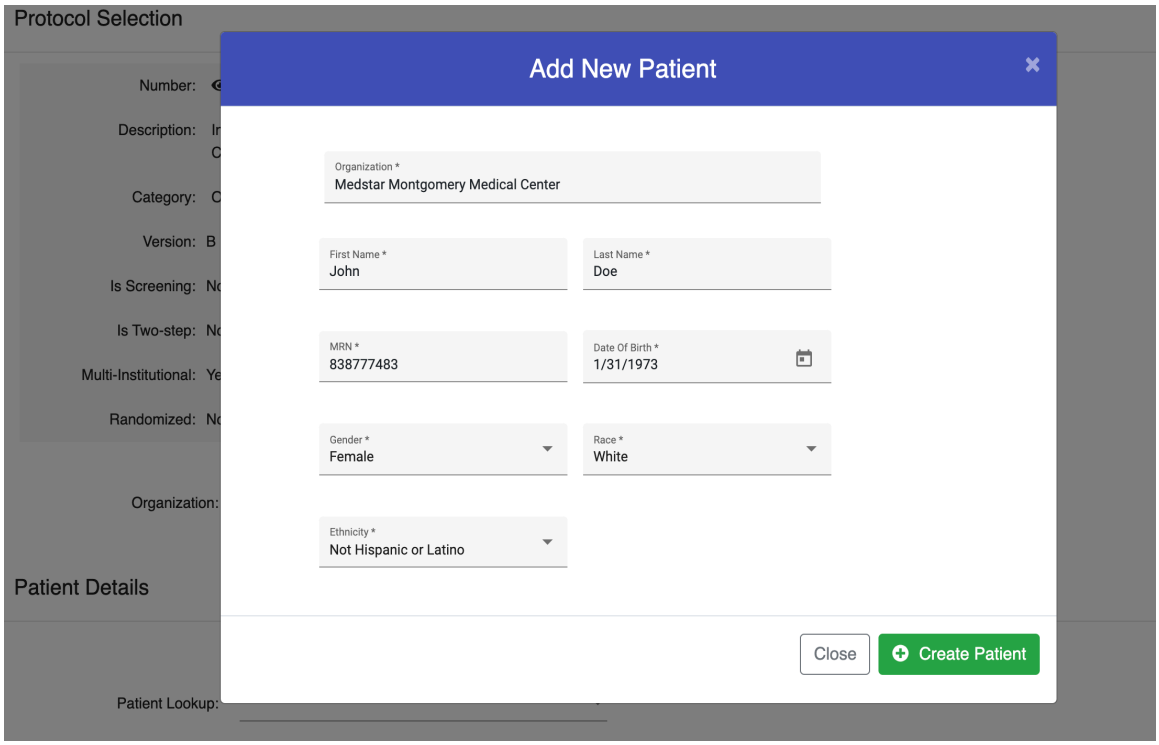


FIGURE 10 – CREATE PATIENT

PATIENT VIEW

The Patient View page displays patient information such as demographics, the protocols in which the patient is participating, and the medical records for each institution that the patient is been treated by.

Patient participating protocols table shows patient enrollments from PRES and CDR applications. Enrollment with PRES value in source column present in PRES and CDR source enrollment retrieved from CDR. However only PRES protocols and enrollments can be viewed in detail

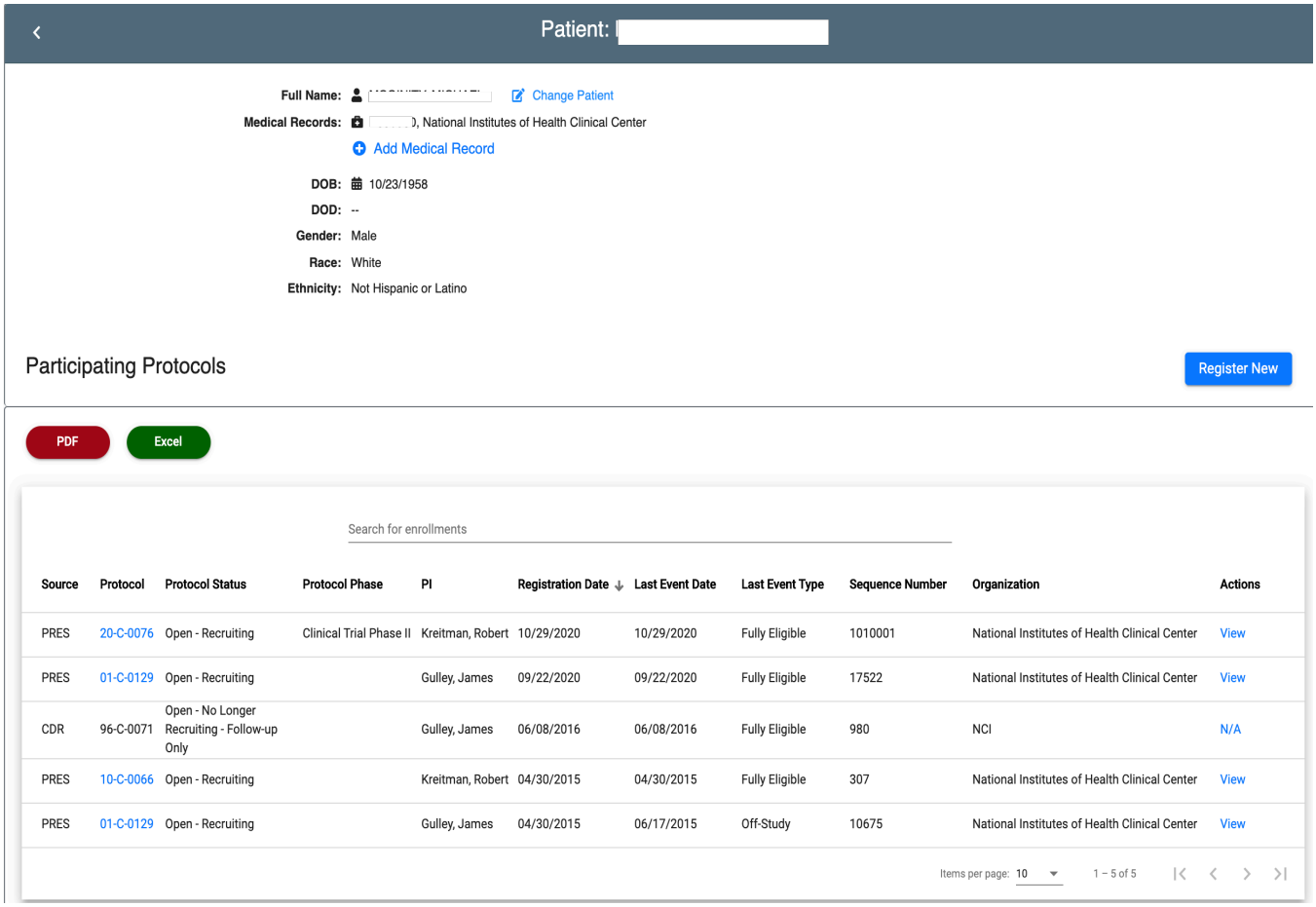


FIGURE 11 - PERSON VIEW

From this view it is possible to modify an existing outside MRN, retrieve protocol data, register the patient to a new protocol, and view the patient's enrollment status for the selected protocol.

ADD MEDICAL RECORD

Clicking the "Add Medical Record" button of the details section of the person view allows the user to add an outside institution's MRN to the selected patient. This section also allows to edit existing outside MRNs. CRIS

MRNs can NOT be modified as they are validated against CRIS. PRES will ensure that MRNs are unique within an institution.

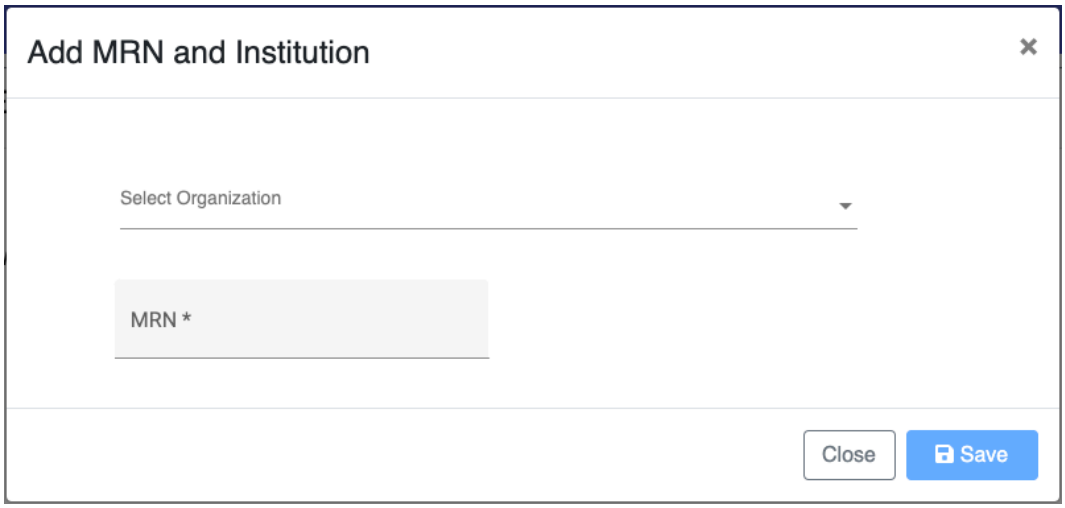


FIGURE 12 - ADD OR MODIFY MRN

PROTOCOL VIEW

The protocol view page displays the available information for the protocol. For a detail of the available information please see the figure below:

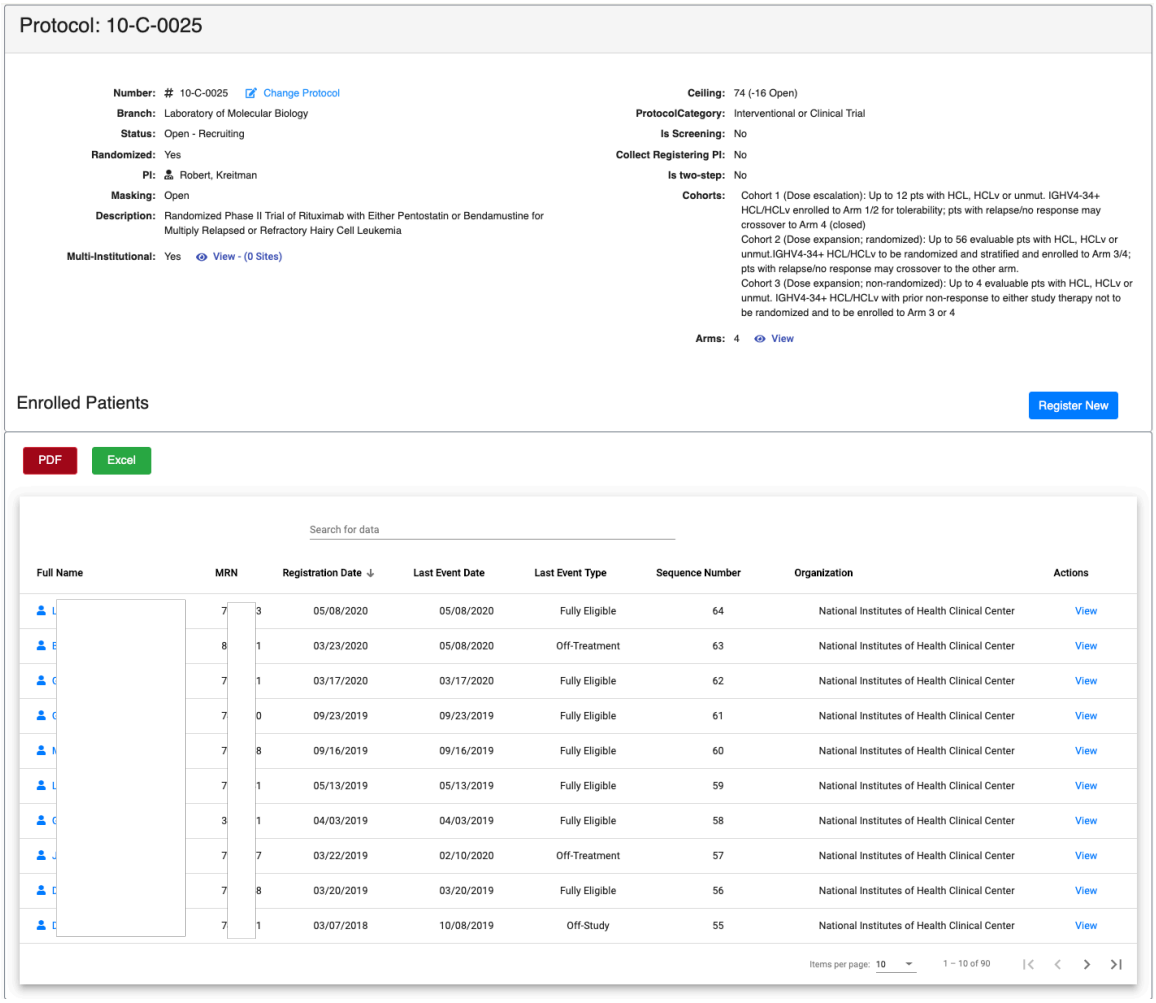


FIGURE 17 - PROTOCOL VIEW

SEARCHING AND SELECTING A PROTOCOL

To find a protocol click on the “Search for a Protocol” field and enter at least 2 characters which will open a drop-down list of protocols already in PRES matching those characters:

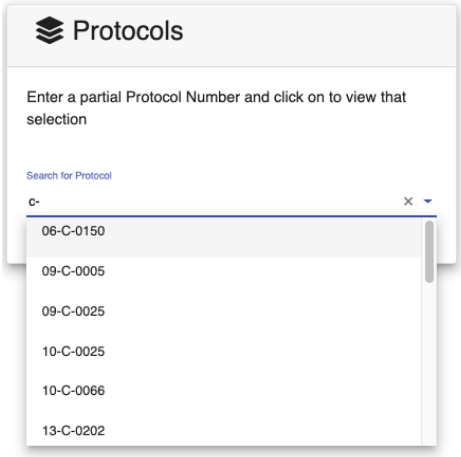


FIGURE 16 - PROTOCOL SEARCH

Clicking on a protocol will open the Protocol View page.

CREATING A REGISTRATION

A registration can be created from the Patient View or the Protocol View as illustrated below by clicking the "Register New" button to the right of the "Participating Protocols" or the "Enrolled Patients" header.

In both cases, after selecting the "Register New" button, the user will be redirected to the Register Patient page.

REGISTER PROTOCOL FROM PATIENT PAGE

Since the patient is already selected the protocol must be selected by clicking on the "Search for a Protocol" field and entering at least 2 characters which will open a drop-down list of protocols already in PRES matching those characters:

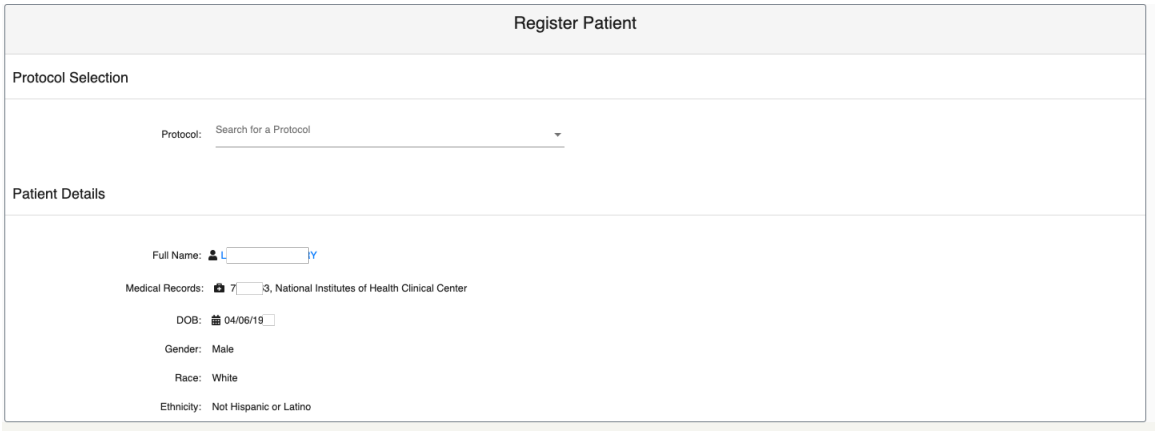


FIGURE 18 - REGISTER PROTOCOL TO PATIENT PAGE

The protocol will be selected by clicking the desired protocol from the results drop down. After selecting the protocol, a summary of the protocol's information will be displayed. This information also notifies the user if it is open to enrollment or not.

In the figure below the selected protocol is not open for enrollment. The error banner in red explains the reason. In this case there are no cohorts available in the protocol.

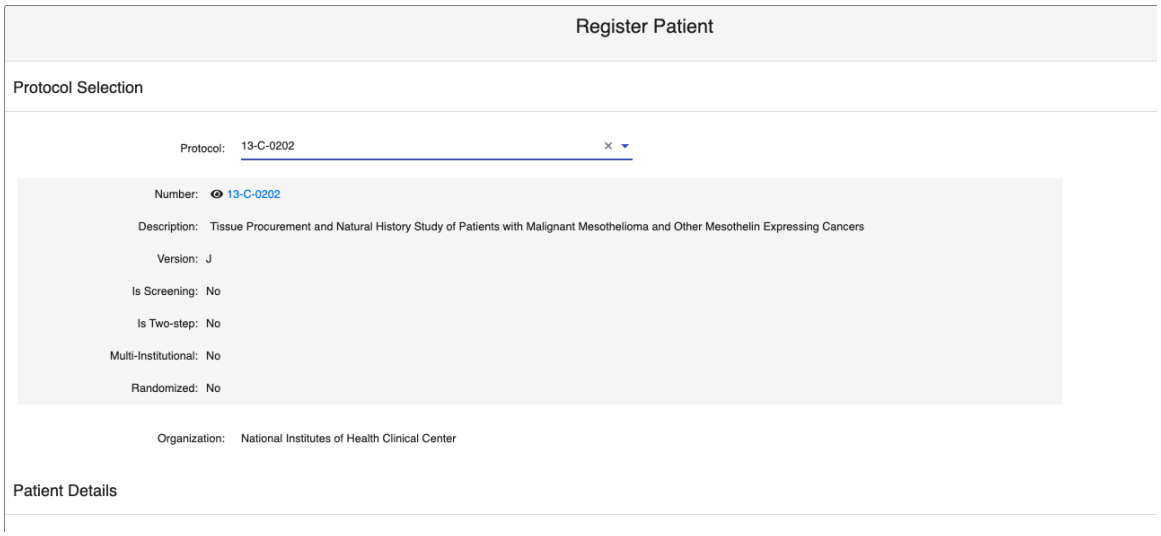


FIGURE 19 – REGISTER PROTOCOL TO PATIENT

REGISTER PATIENT FROM PROTOCOL PAGE

PRES also allows a patient to be added to a protocol from the protocol page

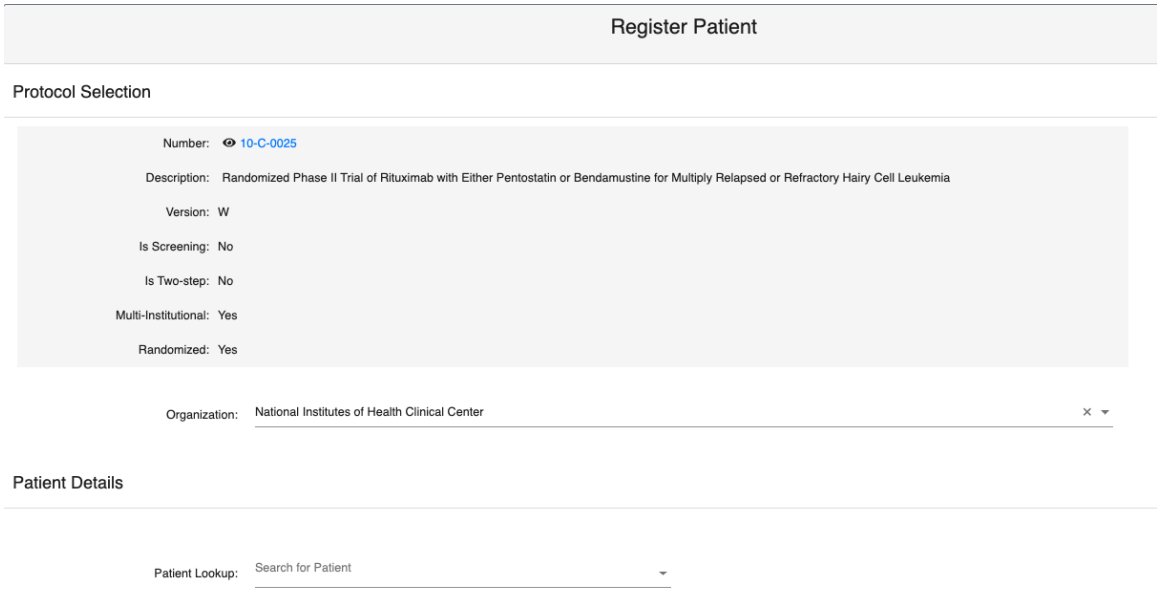


FIGURE 20 - REGISTER PATIENT TO PROTOCOL PAGE

Since the protocol is already selected the user must use the “Search for a Patient” field to select a patient.

Once the Patient and Protocol are selected the user can proceed to provide additional details on the Register Patient page which is dynamic and displays additional fields as data is entered. The Register button will remain inactive until all fields have been populated.

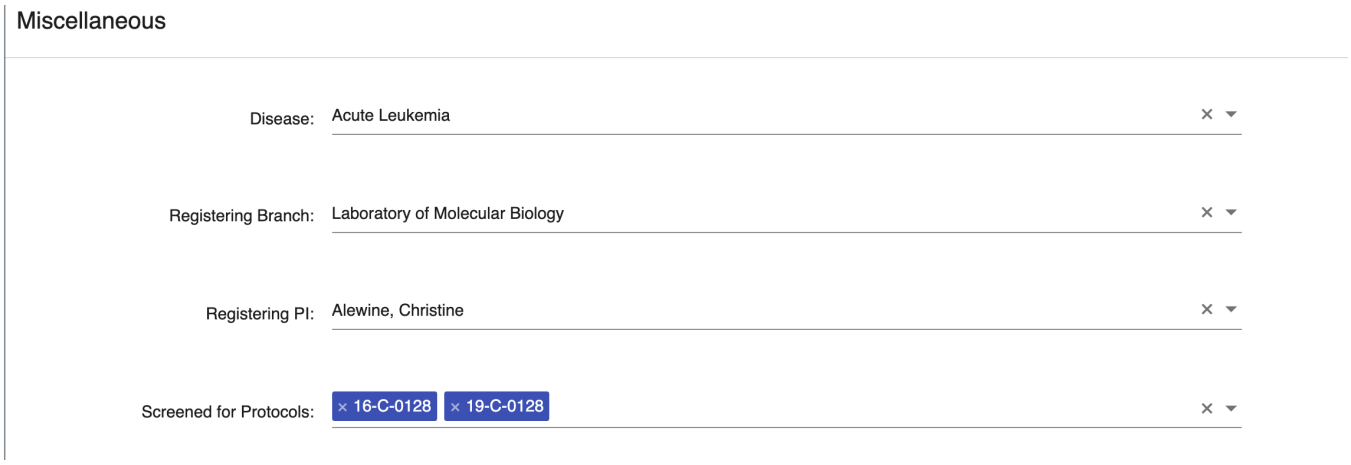


FIGURE 21 - REGISTER PATIENT TO PROTOCOL PAGE

In miscellaneous section Disease input required and Registering Branch, Registering PI and Screened for Protocols inputs are only shown and required for screening protocols i.e. 01C0129

Once the Eligible for Treatment box is checked the Cohort selection field will be displayed.

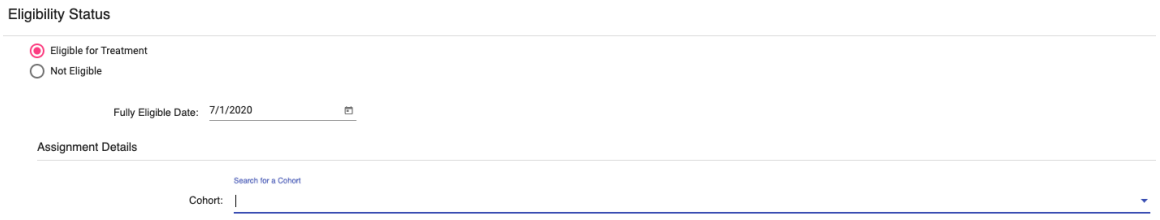


FIGURE 22 - REGISTER PATIENT TO PROTOCOL PAGE

After selecting a Cohort, the Arm selection field is displayed showing only the selected cohort's arms.

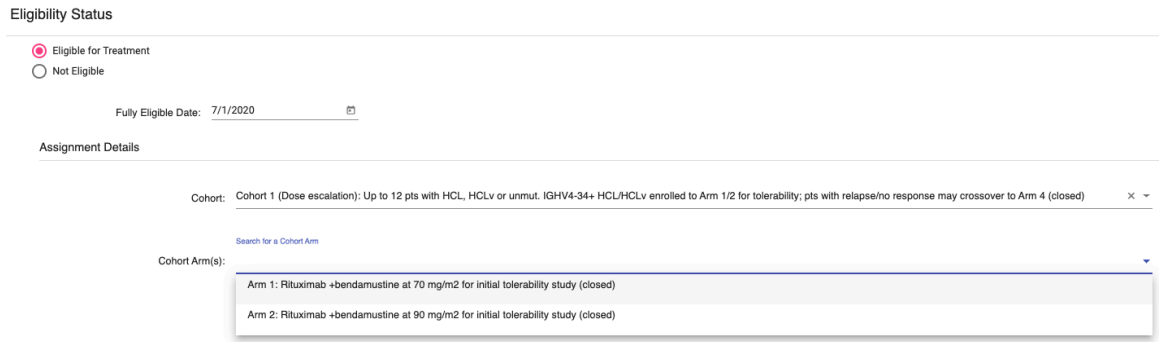
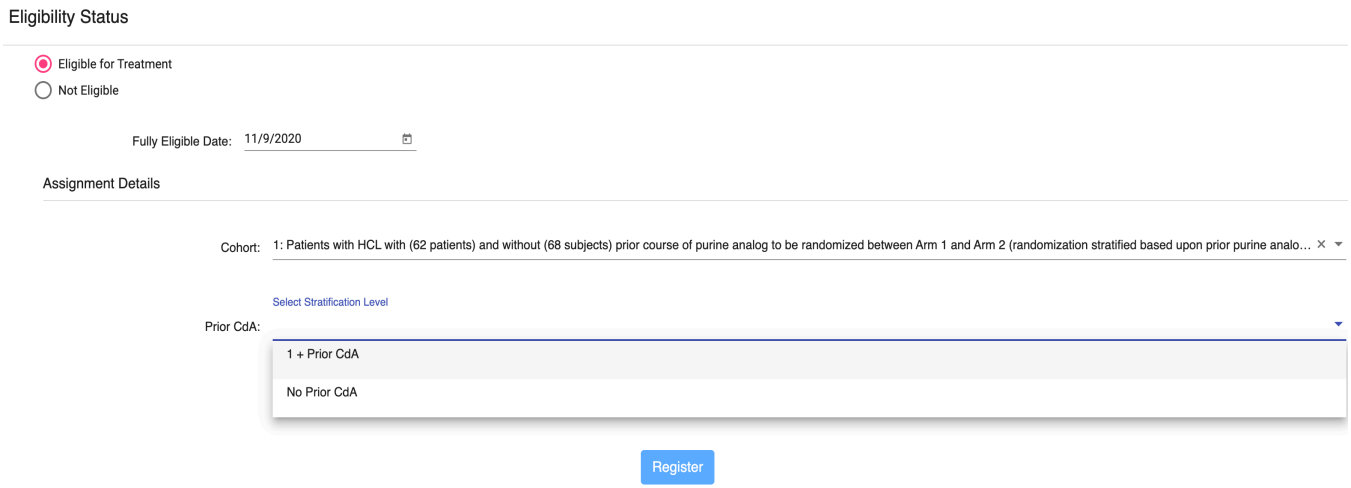


FIGURE 23 – SELECT ARM

Once all fields have been populated the Register button will be activated. The registration will be recorded after clicking the Register button. After successful registration the user will be taken to the Enrollment View.

RANDOMIZATION

For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary. Protocols are randomized in one of the 2 ways, Stratified and Non-Stratified. For Stratified protocols, Cohort, Stratification Factor question and answer must be selected. For Non-Stratified protocols just Cohort selection is required.



TWO STEP AND THREE STEP PROTOCOLS

For two step and three step protocols the Eligibility Status includes the “Eligible for Screening” option.

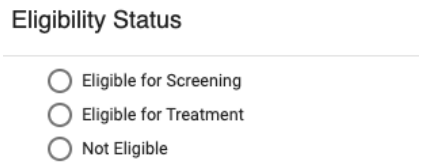


FIGURE 24 – TWO STEP

After screening the Eligibility Status can be updated to Eligible for Treatment or Not Eligible.

ENROLLMENT VIEW

The enrollment view shows the patient's status of the enrollment for the selected protocol. This section can only be accessed re by clicking the view icon in the participating protocols (Patient view) or enrolled patients (protocol view).

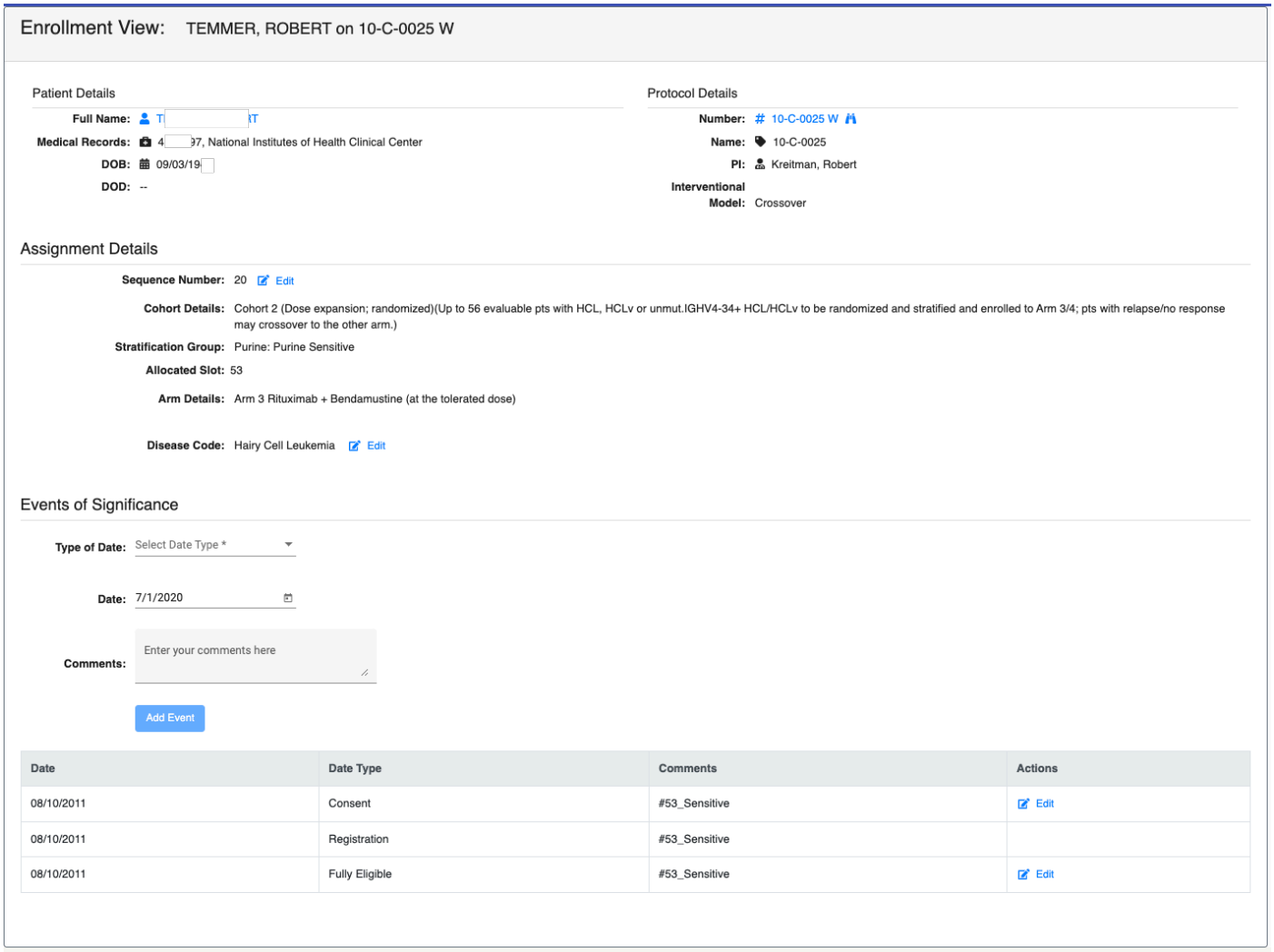


FIGURE 13 - ENROLLMENT VIEW

By clicking in the patient name the user will be redirected to the Patient View, clicking in the protocol number will show the Protocol View.

It is also possible to add/edit the Sequence Number, add/modify the dates of the events of significance, for the patient in the selected protocol.

While editing the Sequence Number the next available sequence number is displayed along with a link to Use This Number.

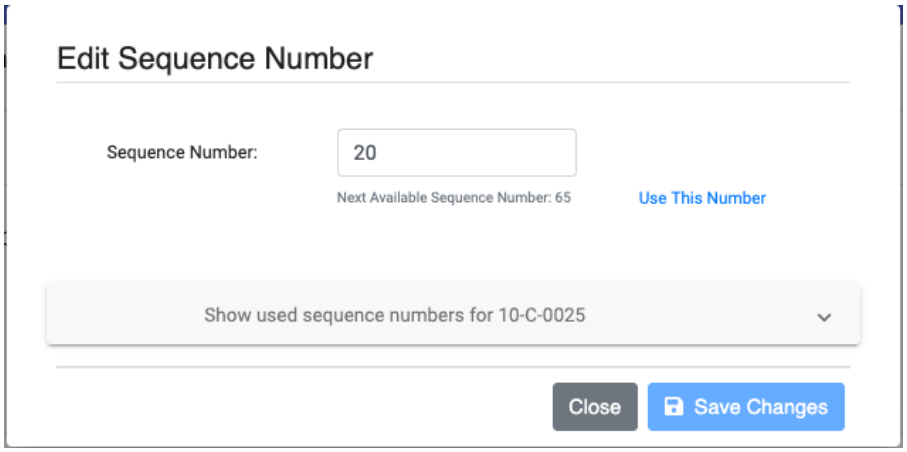


FIGURE 14 – SEQUENCE NUMBER

In addition, there is an option to view the existing Sequence Numbers in this Protocol.

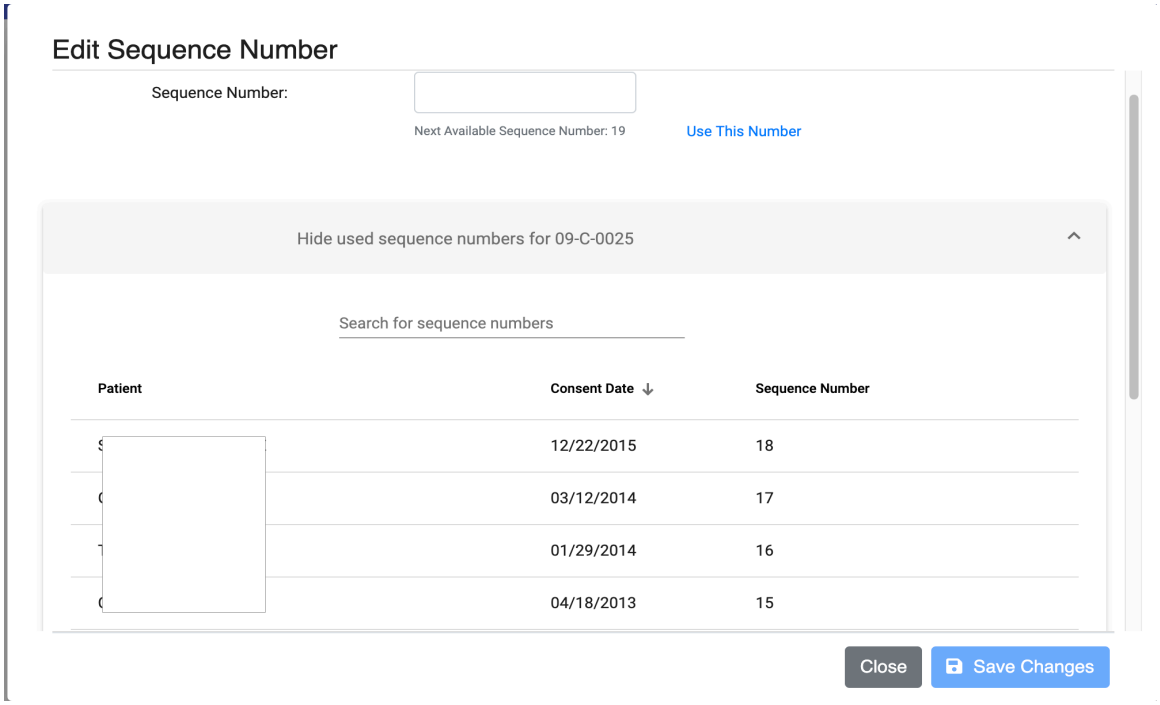
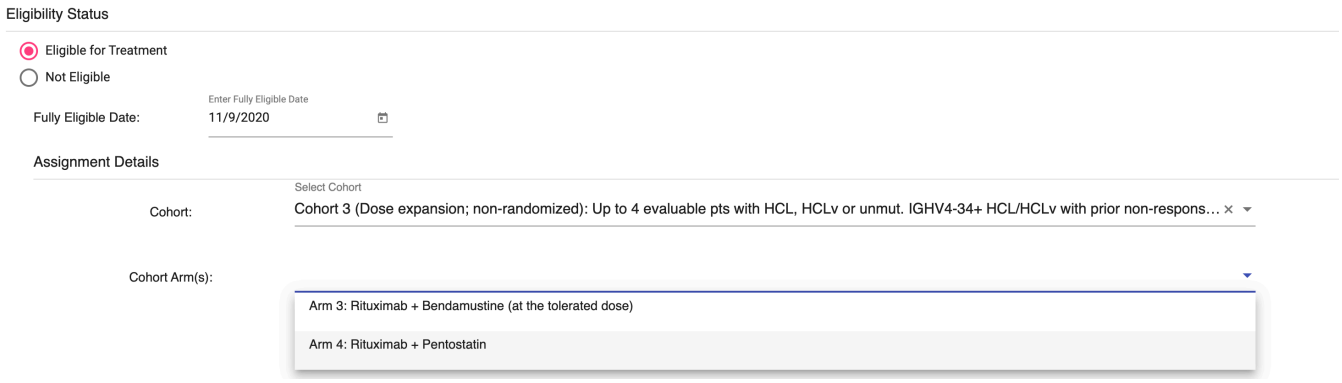


FIGURE 15 – USER SEQUENCE NUMBERS

TWO STEP PROTOCOLS

Patients registered with Eligible for Screening option during initial registration for 2 step and 3 step protocols are eligible receive treatment. Patient Cohort/Arm can be selected on enrollment view. For randomized protocols Cohort (and stratification information for stratified protocols) needs to be selected.



Checking Not Eligible will prompt the user to confirm that the patient should be taken off study. These patients counted as screen failure

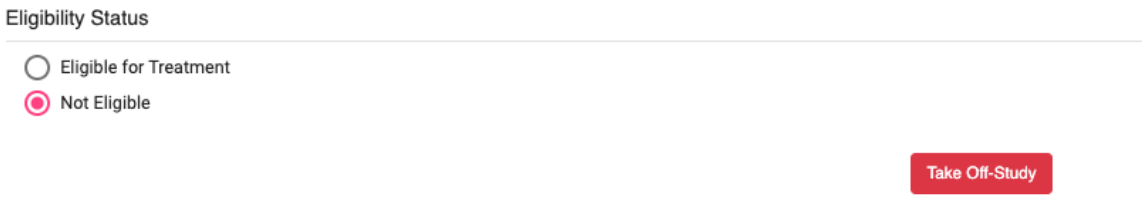
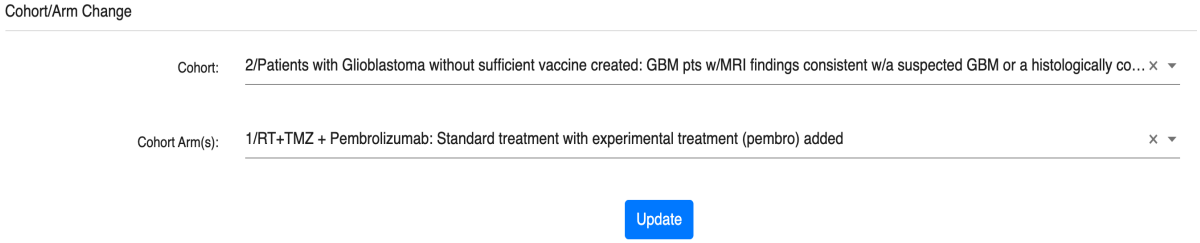


FIGURE 25 – NOT ELIGIBLE

THREE STEP PROTOCOLS

Three step protocols follow the same process as two step protocols and in addition they have 3rd step, in which patient assigned to different Cohort and Arm.



For example, 17-C-0034 is three step protocol with three steps

1. Screening
2. Radiation Therapy
3. Receive Treatment

Patients are initially screened to the protocol, then receive radiation therapy and receive actual treatment in 3rd step

RANDOMIZATION

For randomized cohorts the arm will be assigned as per the randomization sheets and blinded as necessary. Protocols are randomized in one of the 2 ways, Stratified and Non-Stratified. For Stratified protocols, Cohort, Stratification Factor question and answer must be selected. For Non-Stratified protocols just Cohort selection is required.

In masking(blinding) protocols, if the enrollment blind is broken, users with appropriate privilege can Skip the assigned slot for the next available after providing a justifying comment.

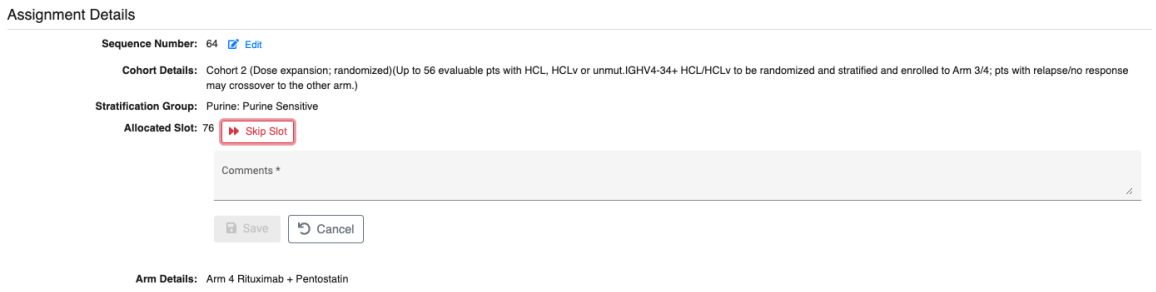


FIGURE 26 - SKIP

EVENTS OF SIGNIFICANCE

The Enrollment View shows the assignment details for a particular patient on a particular protocol.

CROSSOVER PROTOCOLS

Certain protocols allow patients to crossover from one arm to another in the same cohort. For such protocols the Crossover Event of Significance is available until the patient is take Off Treatment.

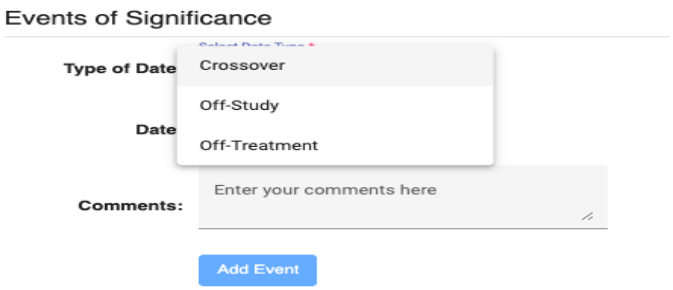


FIGURE 27 - CROSSOVER

TREATMENT PROTOCOLS

All registrations on treatment protocols have the following Events of Significance

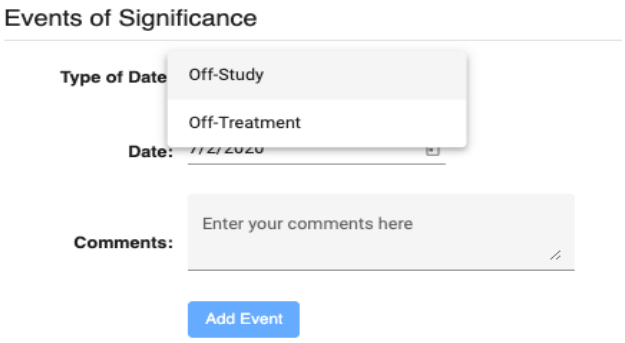


FIGURE 28 – OFF EVENTS

The Enrollment View displays the history of Events off Significance and allows users to edit the comments.

Date	Date Type	Comments	Actions
03/07/2018	Consent	Refractory_NonRandomized	Edit
03/07/2018	Registration	Refractory_NonRandomized	
03/07/2018	Fully Eligible	Refractory_NonRandomized	Edit
10/08/2019	Off-Study	Refractory_NonRandomized	Edit

FIGURE 29 – HISTORY OF EVENTS

REPORTS

This option allows the user to run a series of pre-determined reports within PRES.

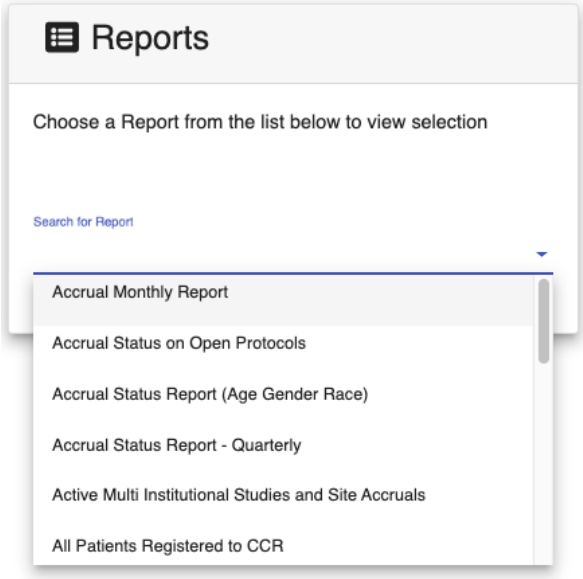


FIGURE 30 - REPORTS

Many of the reports accept parameters including Branch and Protocol.

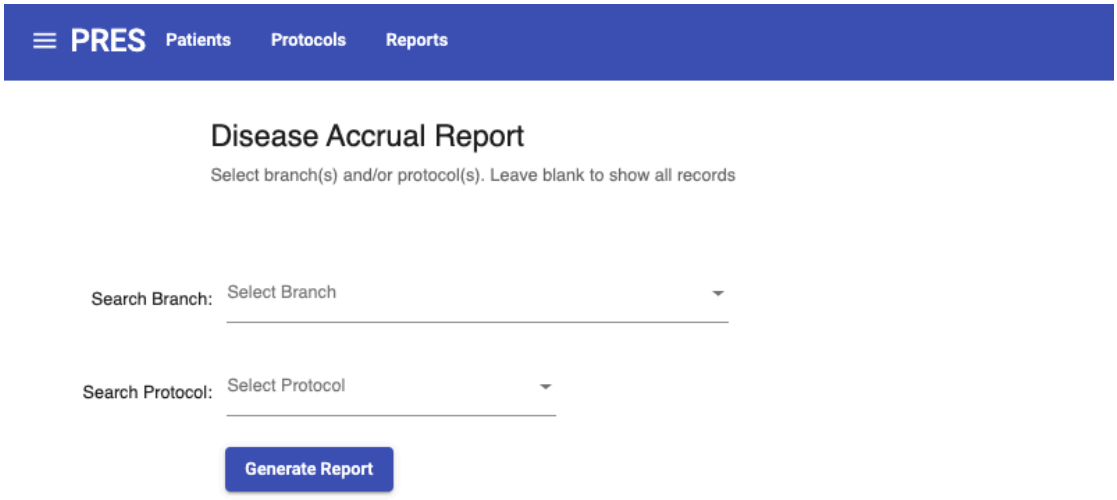


FIGURE 31 – REPORT PARAMETERS

On some reports these parameters are optional, and the report can be generated for all protocols. Some reports have date parameters.

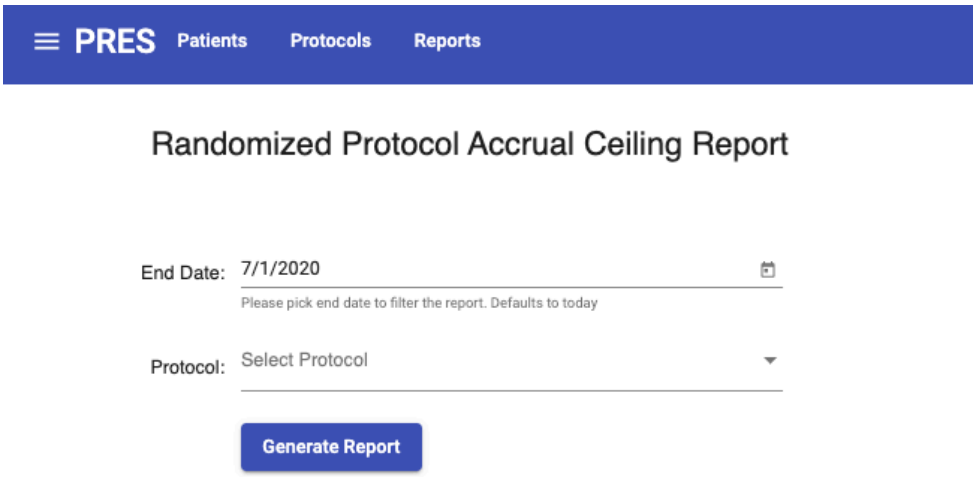


FIGURE 32 – REPORT DATE

One PRES report currently allows the user to Include CDR Data. This is the Accrual Monthly Report as it needs to include all accruals whether in PRES or CDR.

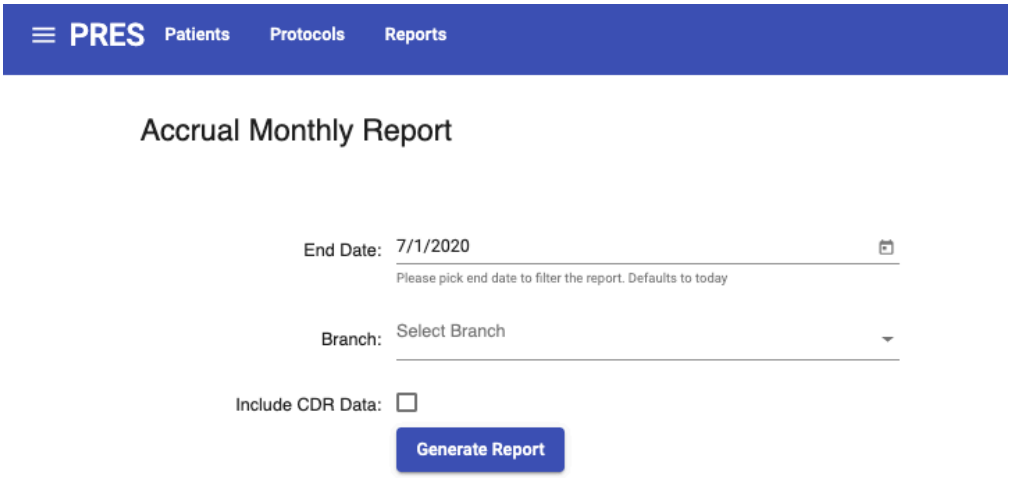


FIGURE 32 – CDR DATA

When selecting to include CDR data there is another checkbox to indicate whether the CDR data to include should be Limited to Active Treatment protocols.

Following is the result page for the Randomized Protocol Accrual Ceiling report:

Randomized Protocol Accrual Ceiling Report

End Date: 7/1/2020

Please pick end date to filter the report. Defaults to today

Protocol: Select Protocol

Generate Report Print

NCI CONFIDENTIAL CCR

Randomized Protocol Accrual Ceiling Report

Reporting Period Ending: 07/01/2020

Report generated on: 07/01/2020 15:46 PM

Protocol	PI	Ceiling	Arm Name	Arm Description	1st On-Study Date	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Cumulative Accrual
10-C-0025	Robert, Kreitman	74								
			Arm 1	Rituximab +bendamustine at 70 mg/m2 for initial tolerability study (closed)	06/23/2010	0	0	0	0	6
			Arm 2	Rituximab +bendamustine at 90 mg/m2 for initial tolerability study (closed)	11/10/2010	0	0	0	0	6
			Arm 3	Rituximab + Bendamustine (at the tolerated dose)	06/22/2011	1	0	2	0	28
			Arm 4	Rituximab + Pentostatin	06/24/2010	1	0	0	1	24
						2	0	2	1	64
09-C-0005	Robert, Kreitman	177								
			1	Cladribine with immediate Rituximab	04/06/2009	1	0	0	0	62
			2	Cladribine with Rituximab delayed by at least 6 months after Cladribine if and when minimal residual disease is detected	04/02/2009	0	0	0	0	59
			3	Non-randomized group receving Cladribine with immediate Rituximab (before rather than after the 1st of the 5 daily doses of cladribine on day 1)	04/22/2009	0	0	0	0	44
						1	0	0	0	165

FIGURE 33 - RANDOMIZED ONLY WITH ARMS REPORT

ISSUES AND FEEDBACK

Clicking the “Need Assistance?” link at the bottom of every page opens a dialog box that allows the user to report issues or suggestions regarding the use of the application.

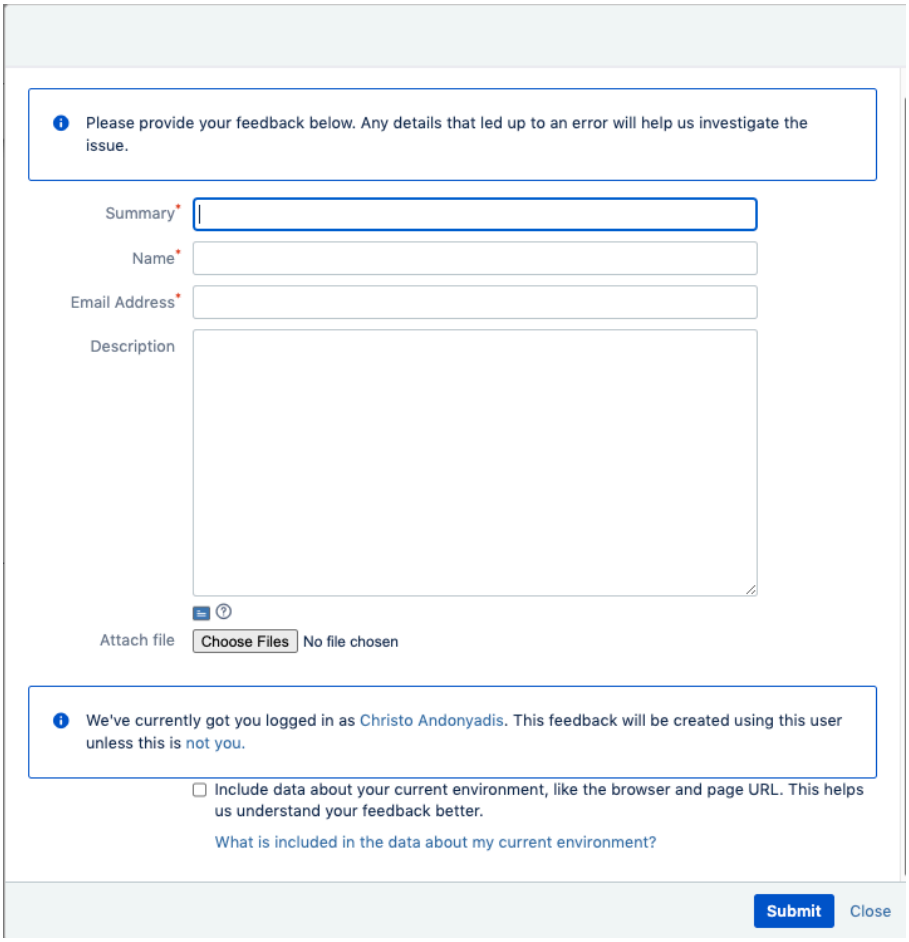


FIGURE 34 - ISSUES AND FEEDBACK

We recommend checking the “Include data about your current environment” box if the assistance is needed for a particular protocol or patient or report. The Office of Information Technology (OIT) will receive the feedback, the user will be identified as the reporter of the issue and receive an email confirming that the ticket has been received.

TABLE OF FIGURES